

CARDIAC VALVE REPLACEMENT WITH BIOLOGICAL VALVES

Analysis of Cases Operated Upon at The Cardiothoracic
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THESIS

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INTRODUCTION

Historic Aspects of Cardiac Valve Replacement

In the early 1950s, Dr. Charles Hufnagel of Washington and Dr. J. Moore Gamphell of Oklahoma City independently developed a new approach to the management of aortic insufficiency in experimental animals. Both designed artificial valves consisting of a lucite tube and a mobile spherical poppet. These devices used the Caged-ball valve principle. Both inserted their valves into the descending thoracic aorta of dogs and improved the haemodynamic abnormalities of aortic valve incompetence.

On September 11, 1952 Hufnagel ignited the fire of prosthetic valve implantation by successfully inserting the ball and cage valve into the descending thoracic aorta of a patient with severe aortic regurgitation. Soon after this, (1956), Murray used a similar technique to implant homograft aortic valve segments in the same position used by Hufnagel.

In 1953, Dr. John Gibbon excited the entire field of medicine by his announcement of the first successful use of total cardiopulmonary bypass for intracardiac surgery in man.

In 1956, Dr. C. Walton Lillehei revitalized the surgical approach to chronic valvular disease by per-

forming the first successful open mitral commissurotomy followed by open annuloplasty operations for severe mitral regurgitation in the same year initiating a new era for reconstructive valvular surgery.

The selective combination of closed-heart operations for valvular heart disease resulted in improved palliation for a large number of patients in the middle and late 1950s. However, many valves were too Shrunken, Calcified, and immobile to allow adequate repair, and it soon became obvious that development of implantable valve substitutes would be absolutely necessary.

The preliminary efforts toward this goal were those in which partial replacement with a mobile prosthesis was evaluated. None of these partial valve replacement techniques were successful because of problems with dehiscence, thrombosis, and loss of compliance of the leaflets. Also, it was evident that the entire aortic or mitral valve often was severely diseased, and thus total, rather than partial valve replacement was necessary.

As the first conference on prosthetic valves for cardiac surgery in September 1960, Many valves were

described like leaflet valves, the flap or monocusp valve, butterfly - Wing, Sleeve, bicuspid and quadricuspid valves. Among the materials employed were Nylon, Dacron, Teflon, Marlex, polyurethane, Lucite, Steel and Ivalon. The overall clinical results with all of these early techniques for total heart valve replacement were poor. The operative mortality rates were exceedingly high, and in those patients who survived surgery, complications frequently occurred shortly thereafter e.g., Prosthesis thrombosis, peripheral emboli, haemolysis and valve dehiscence. At that meeting Dr. Dwight Harken reported survival in two of the seven patients in whom he had implanted a ball valve in the subcoronary position for severe aortic insufficiency.

Ten days after the meeting in Chicago, on September 21, 1960 Starr performed the first, Long-term Successful mitral valve replacement with a caged-ball valve in a 52-year-old man with mitral stenosis and regurgitation.

Starr's original ball valve Prosthesis developed in 1960 was a significant development in valve replacement, these initial prothesis have either been abandoned or undergone multiple modifications and other types of cardiac valves were introduced like:

Magovern - Cromie Stureless valve introduced in 1964.,
Smelcof - Cutter orifice valve was introduced in 1964.,
Bjork-Shiley tilting disc valve was introduced in 1969.,
and Lillehei Kaster valves used Since 1971.

Inspite of multiple modifications of Prosthetic valves and the overall good results over many years, all artificial valves wether the cage and ball type or disc types have common withdrawals, the most important is the risk of thromboembolism and the risks of continuous anticoagulation for life. Being a foreign body they are liable to Catch infection and strict precautions against infective endocarditis for life is a must. Blood haemolysis especially with paravalvular leak may occur in some patients. The artificial valves, of any type, are far from ideal as regards the pattern of blood flow especially during exercise and pressure gradient across the valve is usually present.

A better alternative to artificial prosthesis was continuously searched for: In 1955, Conrad Murray began a successfull series of fresh homograft aortic valve implantations in the descending thoracic aorta of man.

Ross (1962) and Barrat-Boyes, in the Same year, independently performed the first successfull orthotopic implantations of a homograft valve, thereby opening a major pathway in the field of heart valve replacement. Senning

(1962-1967) Successfully used autologous unsupported fascia lata to replace the aortic cusps. Ionescu (1971) used a mounted autogenous fascia lata. However, both types of fascia lata proved to be away from ideal for valve replacement because of the rapid deterioration of the cusp quality with thickening, shrinkage and perforations in addition to the high susceptibility for infective endocarditis. So autologous valves whether fascia lata or pericardium were rapidly abandoned. Ross (1968) was the first to use the patients own pulmonary valve as an autologous graft for the aortic position and replaced the donors pulmonary valve with an aortic homograft. Binet (1965) was the first to use pig aortic heterograft in the subcoronary position of man, the valves were preserved in formaldehyde, however, those valves had a tendency to early deterioration. Carpentier was the first to advise the use of glutaraldehyde for valve preservation to increase it's stability and reduce antigenicity of the valve tissue. Now heterografts, mounted on frames, preserved in glutaraldehyde are commercially available e.g. Hancock valve and carpentier - Edwards valve. The dura mater was used as a homologous graft for valve replacement, but its longterm durability is still considered.

Both types of cardiac valve prosthesis whether artificial or biological (tissue valves) has its own advantages, disadvantages and indications for use.

Artificial prosthesis are in common use with long-term durability, good flow characters, inspite of being away from ideal, and low cost in comparison to xenografts.

Their major disadvantages are

1. Thromboembolic complications.
2. Anticoagulants for life and their hazards.
3. Haemolysis.
4. Susceptibility for infective endocarditis
5. Liability for sudden deterioration and failure.
6. Pressure gradients and less than ideal flow character.

All tissue valves have the following advantages:

1. No or short term anticoagulation.
2. No or minimal thromboembolism.
3. No or minimal haemolysis.
4. Perfect flow characters and minimal pressure gradient.
5. Gradual deterioration, if it occurs, allowing elective intervention under optimum conditions.
6. Low cost, except xenografts.

The major disadvantage of tissue valves is their susceptibility to deterioration due to degenerative process of the cusp tissue with variable durability.

REVIEW OF LITERATURE

Aortic Valve Homograft

The aortic valve homograft was the first type of tissue valves used as cardiac valve substitute in man when G. Murray, in 1955 began a successful series of fresh homograft aortic valve implantations in the descending thoracic aorta of man with established satisfactory function for at least six years. Duran and Gunning at Oxford devised the surgical technique for subcoronary implantation of homograft aortic valves and demonstrated satisfactory function. During 1962, D. Ross in England and Sir B. Barrat-Boyes in New Zealand independently performed the first successful orthotopic implantations of a homograft valve.

Collection and Sterilization of Homografts

The valves, generally, have been obtained between 4 to 48 hours after death excluding those from cadavers whose death were associated with septicæmia. The grafts are generally collected under clean, rather than sterile, conditions. Excess muscle was trimmed from the aorta, the valve was examined for gross congenital or acquired defects (Angell et al 1973). The latest and most commonly used method of homograft sterilization is immersion of the valve in antibiotic solution. Several

antibiotic sterilization techniques evolved employing similar drugs at dissimilar concentrations or different antibiotics at varying dose levels with satisfactory results. (Barrat-Boyes et al., 1969). Sterilization using irradiation or chemical methods was excluded because of the damage produced in the valve structure. (Wain WH., 1972).

Storage of the homografts:

Fresh valves sterilized in antibiotics remain viable for varying periods, this provides a mean of self-repair of the valve structure and offers the prospect that the valve could become a permanent replacement. Comparing the viability between valve tissues exposed to antibiotic in Hank's solution with those exposed to antibiotic-nutrient solutions shows that active metabolism in valves placed in the nutrient medium persisted for a longer storage time. (Al-Jarabi and Ross, 1974) The best antibacterial results were obtained with the following mixture: (Longmore and Starr, 1979)

- Penicillin 1000 Ug/ml.
- Gentamycin 1000 Ug/ml.
- Polymixin B 10 Ug/ml.
- Nystatin 2500 units/ml.

The bactericidal action of penicillin is greater at 37°C against streptococcus faecalis, so, it was recommended that the valves should be incubated for 24 hours at 37°C. in their antibiotic solutions, before being refrigerated. In 1975, it has become a routine to screen micro-biologically all biological tissues intended for clinical use, including screening for Myco bacteria. Species (Barrat-Boyes and Roche 1977)

Morphological and Pathological changes of aortic valve homograft "Graft Evolution".

The histo-pathology of antibiotic-sterilized homografts appears intermediate between those treated chemically and fresh untreated grafts. Host fibrous sheaths extend onto the leaflets. However, fibroblasts do not infiltrate the entire cusp matrix as they do occasionally in fresh grafts." (Gavin et al., 1973). The absence of immune rejection of the graft was attributed to the insulating effect of lack of direct blood supply from the host to the donor leaflet. However subsequent studies showed endothelial changes in homografts similar to those seen following cardiac transplantation. For practical purposes, it does not appear in man that rejection is sufficiently